

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION)	MDL 2804
THIS DOCUMENT RELATES TO:)	Case No. 1:17-md-2804
Track Three Cases:)	Judge Dan Aaron Polster
County of Lake, Ohio v.)	<u>INJUNCTION ORDER</u>
Purdue Pharma, L.P., et al.,)	
Case No. 18-op-45032)	<u>NUNC PRO TUNC</u>
County of Trumbull, Ohio v.)	
Purdue Pharma, L.P., et al.,)	
Case No. 18-op-45079)	

On August 17, 2022, this Court entered a *Track Three Injunction Order*. See docket no. 4611-1. This *Order* directed pharmacy-defendants Walmart, Walgreens, and CVS to undertake various actions “within 90 days.” *Id.* at 1. However, the Court subsequently stayed implementation of the *Track Three Injunction Order* until February 8, 2023. See non-document Orders dated October 26, 2022, December 1, 2022, and January 4, 2023.

The Court now lifts the stay of the *Track Three Injunction Order* and also amends it slightly *nunc pro tunc*, as set forth below. The main difference between the instant Order and the original *Track Three Injunction Order* is that **the Court** will oversee compliance with this Injunction Order, instead of an Administrator, *see ¶ I.B.* There are also some other minor revisions, *see ¶¶ III.E, VIII.F, IX.B.6, and XVIII.*

Finally, for the reasons explained in a separate Order issued simultaneously, Defendants’ motion for stay of this *Injunction Order* pending appeal (docket nos. 4658 & 4870) is **denied**.¹ However, the Court gives Defendants an additional 10 days to implement the provisions of this Order, *see ¶I.A.* Thus, the original deadline for implementation of the *Track Three Injunction Order* at docket no. 4611-1, which was November 15, 2022, is now instead February 20, 2023.²

¹ Analysis of the defendants’ motion for stay of the injunction order pending appeal is ultimately simple: (1) defendants’ likelihood of success on the merits is middling at best; (2) the likelihood of irreparable harm to defendants is very low; (2) the likelihood of harm to others absent the injunction is very high, based on evidence adduced at trial of repeated failures by defendants to monitor for red flag prescriptions and the complete lack of oversight by corporate personnel; and (4) there is *overwhelming* public interest in the injunctive relief. *See Mich. Coal. of Radioactive Material Users, Inc. v. Grieppentrog*, 945 F.2d 150, 153 (6th Cir. 1991) (listing the four factors). Further, the few provisions in this Order that are not contained in the injunctive relief included in the defendants’ global nationwide settlements are essential to address the harm identified at trial. That the global settlements did not include these provisions (e.g. sharable documentation of refusals to fill) is an unfortunate oversight.

² The Court has thus given defendants a total of 187 days to implement the *Injunction Order*. Walmart has stated that “the terms of the Injunction Order are [already] much like Walmart’s existing policies and procedures.” Supplement at 3

I. INTRODUCTION

A. Within 10 days of the date of this Order (except where this Order specifies a different implementation period), Walmart, Walgreens, and CVS Pharmacy, Inc. (the “Defendants”) shall each implement the terms set forth in this Order (the “Terms”). References below to “a Defendant” or “the Defendant” apply to each of the Defendants individually. References below to “a County” or “the County” apply to each of Ohio’s Lake and Trumbull Counties individually. To the extent a Defendant already has in place committees, departments, policies, or programs that satisfy the terms of this Order, no re-naming is required by this Order.

B. The Court, and not an Administrator, will oversee compliance with this Injunction Order. The appointment of the Administrator to oversee Section VII of the Abatement Order, however, remains in place.³ The Court’s Order Appointing an Administrator (docket no. 4652) is **amended** accordingly.⁴

C. Overview

1. The Defendant will implement or maintain a Controlled Substance Compliance Program (“CSCP”).

2. The CSCP must include written standard operating procedures and/or corporate policies (the “CSCP Policies and Procedures”) required by this Order.

3. The CSCP shall apply during the term of this Order to the Defendant’s retail pharmacy stores within the County.

4. The Defendant shall provide a copy of the relevant CSCP Policies and Procedures to the County and the Court. To the extent any implementation is expected to require additional time, the Defendant shall work together in good faith with the Court to establish a timeline for implementation.

(docket no. 4870). Walgreens has joined Walmart’s supplement, *see* docket no. 4874. Thus, the obligation this Order imposes on Defendants is not onerous.

³ The Pharmacy Defendants objected to appointment of the Administrator to oversee the Injunction Order, but did not object to the Administrator’s oversight of Section VII of the Abatement Order.

⁴ Specifically: (1) the following language at page 2 of the Appointment Order is modified by striking and adding the wording shown here: “The Administrator[3] shall undertake the duties set out in Section VII of the Abatement Order, ~~and shall also oversee compliance with all aspects of the Injunction Order. With respect to the Abatement Order only,~~ the Administrator shall have”; and (2) the following language at page 3 of the Appointment Order is modified by striking the language shown here: “Thus, the Administrator’s duties regarding oversight of the funds payable by defendants under the Abatement Order are on hold, ~~but his duties regarding oversight of the conduct required by defendants under the Injunction Order remain operative and are not postponed.~~”; and (3) the following language at page 3 of the Appointment Order is modified by striking the language shown here: “assist the Court with mediating resolution of any part of any dispute related to the Abatement Order ~~or Injunction Order or any other Court order....~~”.

D. Compliance with Laws

1. The Defendant's retail pharmacies must comply with applicable federal and Ohio state laws, including regarding the dispensing of Controlled Substances. The requirements of this Order are in addition to, and not in lieu of, any other requirements of federal or Ohio state law. Nothing in this Order shall be construed as relieving the Defendant of the obligation of its retail pharmacies to comply with all federal and Ohio state and local laws, nor shall any of the provisions of the Order be deemed as permission for the Defendant to engage in any acts or practices prohibited by such laws.

2. The Order is not intended to and shall not be interpreted to prevent the Defendant from taking or implementing any other compliance or policy steps necessary to address their retail pharmacies' conformity with local, state, and federal legal requirements.

3. In the event that the Defendant determines there is a conflict between the Order and the requirements of federal, state, or local laws, such that the Defendant determines it cannot comply with the Order without violating these requirements, the Defendant shall document such conflicts and notify the County and the Court that it intends to comply with the law to the extent necessary to eliminate the conflict. Within thirty (30) days after receipt of a notification from the Defendant referenced above, the County may request a meeting to discuss the conflict and the Defendant shall comply with any such reasonable request. In the event that the Defendant and the County cannot agree, they may seek relief and a resolution from the Court. Nothing in this paragraph shall (i) limit the right of the County to disagree with the Defendant as to the impossibility of compliance and to seek to enforce the Order accordingly; or (ii) be deemed to relieve the Defendant from following any subsequently enacted law that is more restrictive than the provisions of the Order, or from following the Order if they are more restrictive than applicable laws, to the extent the Defendant can adhere to both the Order and the provisions of local, state or federal law.

4. In the event that any action, administrative or otherwise, is commenced against the Defendant, any of its retail pharmacies, or its pharmacy personnel as a result of the Defendant's obligations under this Order in a County—including but not limited to actions brought by State Boards of Medicine and Pharmacy or the State Department of Health—the County will make best efforts to intervene and seek dismissal or to otherwise assist in achieving resolution, including by certifying that the County's position is that the Defendant should not be held liable for actions required by this Order.

5. The Defendant shall retain all records it is required to create pursuant to their obligations hereunder in an electronic or otherwise easily accessible format for the term of this Order. Nothing in this Order shall waive any applicable privilege that may be asserted over any such record.

II. TERM AND SCOPE

- A. The term of the Order shall be 15 years from the Effective Date, unless otherwise specified herein.
- B. This Order shall apply to the Defendant's operation of any retail pharmacy store that dispenses Controlled Substances to Patients within a County.

III. DEFINITIONS

- A. The term "Controlled Substances" means those substances designated under schedules II-V pursuant to the federal Controlled Substances Act and the laws and regulations of the State that incorporate the federal Controlled Substances Act.
- B. The term "Designated Controlled Substances" shall include: (a) oxycodone; (b) hydrocodone; (c) hydromorphone; (d) oxymorphone; (e) morphine; (f) methadone; and (g) fentanyl.
- C. The term "Prescriber" means any individual that has written a prescription, whether legally valid or not, that is presented to one of the Defendant's retail pharmacy stores in a County.
- D. The term "Patient" means any individual who receives a prescription for a Designated Controlled Substance from a Prescriber, whether legally valid or not, and attempts to fill it at one of the Defendant's retail pharmacy stores in a County.

IV. CONTROLLED SUBSTANCE COMPLIANCE PERSONNEL

- A. The Defendant shall designate a Chief Controlled Substance Compliance Officer, or other appropriately titled position, to be a member of the Controlled Substance Compliance Committee (described below in Section VI), and to oversee a Controlled Substance Compliance Department and the Defendant's compliance with this Order. As used in this Order, the terms "Controlled Substance Compliance Committee" and "Controlled Substance Compliance Department" refer to the entity or entities, however titled, that carry out the functions required by this Order. Notwithstanding the preceding sentence, to the extent an existing position, committee or department carries out the functions required by this Order, any other functions undertaken by such position, committee or department shall not be subject to this Order or oversight by the Administrator pursuant to this Order. The position, committee and department discussed in this subsection and below may bear different names and need not be limited to the roles and functions set forth herein.

- B. The Chief Controlled Substance Compliance Officer shall have knowledge of and experience with the laws and regulation of Controlled Substances.

C. The Chief Controlled Substance Compliance Officer shall provide at least quarterly reports to the Controlled Substance Compliance Committee and the Court regarding the Defendant's compliance with this Order, including the implementation of any changes to the CSCP Policies and Procedures required by this Order.

D. Staffing levels of the Defendant's Controlled Substance Compliance Department shall be reviewed periodically, but at least on an annual basis, by the Defendant's Controlled Substance Compliance Committee, to assess whether such staffing levels are sufficient for the Controlled Substance Compliance Department to comply with this Order. This review shall include consideration of relevant developments in technology, law, and regulations.

E. Throughout the term of this Order, the Defendant shall maintain a telephone and email hotline(s) (the "Hotline") to permit employees and/or Patients to anonymously report suspected inappropriate or illegitimate dispensing, prescribing or diversion of Designated Controlled Substances, violations of the CSCP Policies and Procedures, this Order, the Defendant's company policy, or other applicable law. The Defendant shall publish its Hotline contact information to its employees and Patients in the County. The Defendant shall maintain for the duration of this Order a record of each complaint made to the Hotline regarding Designated Controlled Substances and documentation regarding any investigation or response to such complaints. Nothing herein shall require the Defendant to investigate a pharmacist's professional judgment to refuse a prescription that the pharmacist believes was prescribed or is being used for other than a legitimate medical purpose or that the pharmacist believes was not prescribed by an individual Prescriber acting in the usual course of his or her professional practice.

V. INDEPENDENCE

A. The Defendant's Controlled Substance Compliance Department personnel, the pharmacy personnel who work at the Defendant's retail pharmacies within the County, and field personnel who supervise such pharmacy personnel (together, "CSCP Employees") shall not be compensated in whole or in part by commissions, bonuses, incentives or any other monetary or non-pecuniary benefit that depends in any part on revenue or profitability targets or expectations specific to sales of Controlled Substances. Nothing in this Order shall be interpreted to prevent compensation of employees based on sales volumes, revenue or profitability targets/expectations for enterprise-, store- or pharmacy-wide sales.

B. No CSCP Employees may be terminated, suspended, threatened with or face any other negative employment consequence for failing to meet any revenue or profitability targets/expectations specific to sales of Controlled Substances.

C. To the extent necessary to comply with this section, the Defendant's Controlled Substance Compliance Committee shall review, modify, and implement any changes to any compensation and non-retaliation policies specific to the sale or dispensing of Designated Controlled Substances.

VI. OVERSIGHT

A. To the extent not already established, the Defendant shall establish a compliance committee, however titled, that includes representatives from its respective legal, compliance, pharmacy operations, and asset protection departments, however named, to provide oversight over the CSCP and its compliance with this Order. For the purposes of reference herein, this committee, however named, shall be referred to as the “Controlled Substance Compliance Committee.” The Defendant shall maintain its Controlled Substance Compliance Committee for the duration of the term of this Order. The Chief Controlled Substance Compliance Officer of the Defendant shall be a member of the Controlled Substance Compliance Committee.

B. The Defendant’s Controlled Substance Compliance Committee shall have regular meetings during which the Chief Controlled Substance Compliance Officer shall report on, and the Controlled Substance Compliance Committee shall review, among other things, (a) the Prescription Validation Process, including the CSCP Policies and Procedures on identifying and resolving Patient, Prescriber and Prescription Red Flags; (b) the training required under this Order; (c) proactive due diligence and site visits; (d) the Prescriber Review Processes; (e) significant new national and regional diversion trends involving Controlled Substances; (f) the Defendant’s adherence to this Order and applicable laws and regulations; and (g) any technology, staffing, or other resource needs for the CSCP. The Controlled Substance Compliance Committee shall have access to all CSCP reports described in the following subsection.

C. On an annual basis, the Defendant’s Controlled Substance Compliance Committee shall provide a written report to the President, Chief Financial Officer, Chief Legal Officer, and the Chief Compliance Officer (however such positions or committees are named at the time), and the Court, outlining: (a) the Defendant’s adherence to, and any deviations from, this Order; (b) the allocation of resources sufficient to comply with this Order; and (c) any revisions to the CSCP that the Controlled Substance Compliance Committee has approved. The Compliance Committee shall document in its minutes its review of the annual Controlled Substance Compliance Committee reports.

D. The Defendant, through its Controlled Substance Compliance Departments and Committees, shall, at least once every year, review and oversee any enhancements to the CSCP Policies and Procedures and systems for dispensing activity that the Controlled Substance Compliance Committee deems necessary.

E. The Defendant’s Controlled Substance Compliance Committee shall be responsible for the approval of all material revisions to the CSCP Policies and Procedures, provided that nothing herein shall prevent the Defendant from implementing changes to the CSCP Policies and Procedures pending such review and approval.

VII. MANDATORY TRAINING

- A. The CSCP Policies and Procedures shall be published in a form and location readily accessible to all pharmacy and compliance personnel at each of the Defendant's retail pharmacy stores in the County. Online availability is sufficient, so long as pharmacy and compliance personnel have access to a computer with access to the CSCP Policies and Procedures.
- B. Within 90 days of the date of this Order, to the extent not already in place, the Defendant shall implement policies and procedures requiring all CSCP Employees to complete trainings on the CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and its corresponding responsibility.
- C. On an annual basis for the duration of the Order, the Defendant shall test its CSCP Employees, and any contractors serving as pharmacists or pharmacy technicians in its retail pharmacies in the County, on their knowledge regarding CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and their corresponding responsibility.
- D. It shall be a part of the CSCP Policies and Procedures and all trainings of all CSCP Employees required under this Order that pharmacists shall refuse to dispense Controlled Substances that they believe were prescribed or are being used for other than a legitimate medical purpose or that they believe were not prescribed by an individual Prescriber acting in the usual course of his or her professional practice.
- E. All trainings required under this Order shall also make clear that pharmacists will not be penalized in any way for refusing to fill prescriptions for Controlled Substances or for conducting Due Diligence the pharmacist deems necessary pursuant to their corresponding responsibility.

VIII. THE PRESCRIPTION VALIDATION PROCESS

- A. As part of its CSCP, to the extent not already in place, the Defendant shall have a Prescription Validation Process in the CSCP Policies and Procedures, as further described and set forth in this section, that each pharmacist employed by the Defendant at a retail pharmacy in the County is directed to follow when dispensing a prescription for a Controlled Substance.
- B. The Defendant's CSCP Policies and Procedures shall provide that a Red Flag will be considered "resolved" if, after further investigation as described below, and given other facts and circumstances surrounding the prescription, a pharmacist determines, in his or her professional judgment, that the facts that triggered the Red Flag do not lead him or her to believe that the prescription was written or is being submitted for an illegitimate medical purpose or outside the usual course of a Prescriber's professional practice.

C. The Defendant's CSCP Policies and Procedures shall provide that if a pharmacist identifies any "Patient Red Flags" associated with a Controlled Substance prescription (described in Section IX(A) below), before filling the prescription the pharmacist must resolve them; and that the method of resolution falls within the judgment of the pharmacist and may include reviewing the Patient's profile and history with the Defendant, calling the Prescriber or Prescribers if appropriate, speaking with the Patient if appropriate, calling on the pharmacist's pre-existing knowledge of the Patient or Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

D. The Defendant's CSCP Policies and Procedures shall provide that, except as allowed by Ohio law, a pharmacist may only fill a Controlled Substance prescription electronically transmitted by a Prescriber for such drugs; that if the pharmacist identifies any other "Prescription Red Flags" (described in Section IX(B) below), the pharmacist must resolve them; and that the method of resolution falls within the judgment of the pharmacist and may include reviewing the Patient's profile and history with the Defendant, calling the Prescriber or Prescribers if appropriate, speaking with the Patient if appropriate, calling on the pharmacists preexisting knowledge of the Patient or Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

E. The Defendant must put in place, to the extent not already in place, systems at its retail pharmacies in the County to check the licensure status of a Prescriber of Controlled Substances through a regularly updated prescriber database, to the extent such information is reasonably available for such purposes. The dispensing system shall block a Controlled Substance prescription from being filled if the prescriber database check reflects a DEA registration or state license that has been suspended or revoked and likewise shall block from being filled under a Controlled Substance prescription written by a prescriber blocked by the Defendant under a prescriber review program. CSCP Policies and Procedures shall require that if a pharmacist identifies any Prescriber Red Flags, the pharmacist must resolve them, and that the method of resolution falls within the judgment of the pharmacist and may include reviewing the Defendant's records regarding the Prescriber, calling the Prescriber if appropriate, speaking with the Patient if appropriate, calling on the pharmacist's pre-existing knowledge of the Patient or the Prescriber, reviewing available PDMP data, and/or reviewing other data or information available to the pharmacist.

F. The Defendant's CSCP Policies and Procedures shall provide that the resolution of all Red Flags and Refusals-to-Fill identified by the pharmacist must be documented. The pharmacist must provide a clear description of the Red Flag(s) and either (i) how the Flag was resolved before the medication was dispensed, or (ii) the reasons why the pharmacist refused to dispense the medication. The documentation should provide sufficient details in order that any subsequent reviewer will have a clear understanding of how each Flag was resolved for any review or inquiry for auditing or regulatory purposes. The documentation must be available and easily accessible to all pharmacists employed by the Defendant at all of its retail pharmacies. Any such records shall be maintained for the duration of this Order.

G. The Defendant's CSCP Policies and Procedures shall provide that, even if all Red Flags are resolved, a pharmacist shall reject a prescription if, in his or her professional judgment, he or she believes that it was written or is being submitted for other than a legitimate medical purpose and/or was written outside the usual course of an individual Prescriber's professional practice.

IX. RED FLAGS

A. Notwithstanding any other Red Flags that the Defendant may identify in its CSCP Policies and Procedures, the Defendant shall identify in its CSCP Policies and Procedures the following "Patient Red Flags":

1. A Patient seeks to fill a Designated Controlled Substance prescription more than three days prior to the contemplated exhaustion date of an earlier prescription of the same Designated Controlled Substance;
2. A Patient seeks to fill Designated Controlled Substance prescriptions from more than four Prescribers, from separate practices, in a given 6-month period;
3. A Patient resides more than 50 miles from the Defendant retail pharmacy where the Designated Controlled Substance prescription is submitted;

B. Notwithstanding any other Red Flags that the Defendant may identify in its CSCP Policies and Procedures, with respect to any Controlled Substance prescriptions, the Defendant shall identify in its CSCP Policies and Procedures the following potential "Prescription Red Flags:"

1. A prescription that fails to meet the requirements of law, *e.g.*, Ohio Rev. Code § 3719.06.
2. A prescription that appears altered;
3. A prescription written with misspellings suggesting the prescription may not have been written by a Prescriber;
4. A prescription using atypical abbreviations suggesting the prescription may not have been written by a Prescriber;
5. A prescription written with multiple colors of ink or in multiple different handwritings; and
6. A prescription that was previously rejected pursuant to the Prescription Validation Process (*e.g.*, a Refusal-to-Fill).

C. Notwithstanding any other potential Red Flags that the Defendant may identify in its CSCP Policies and Procedures, with respect to any Prescriber of Controlled Substances, the Defendant shall identify in its CSCP Policies and Procedures the following potential “Prescriber Red Flags:”

1. A Prescriber provides a Patient with prescriptions for a Designated Controlled Substance, a benzodiazepine, and carisoprodol; and
2. A Prescriber has no office within 50 miles of the retail pharmacy store.

X. X. PRESCRIBER REVIEW

A. To the extent not already in place, the Defendant shall develop a process by which it regularly reviews the prescribing patterns and practices of Prescribers of Designated Controlled Substances (the “Prescriber Review Process”). The Prescriber Review Process shall employ algorithms, or other means, to review the Defendant’s retail dispensing data for potential Prescribers of concern. Once the Defendant identifies through its process a Prescriber for further investigation, the review of a Prescriber shall include review of his or her prescribing as contained in the Defendant’s data and available licensing and disciplinary history. It may also include internet searches, interviews and other information gathered in the discretion of the employees operating the Prescriber Review Process.

B. If after the Prescriber Review Process the Defendant has not resolved its concerns of illegitimate prescribing, then Controlled Substance prescriptions written by the Prescriber shall be blocked from being filled by the Defendant’s retail pharmacies in the County, with an opportunity at the discretion of the Defendant for the prescriber to seek future reinstatement by providing information to the Defendant that may resolve its concerns. This block shall be on top of and in addition to any block based on a Prescriber’s licensure. On written demand by a County or the Court, the Defendant shall provide the names of the prescribers who it has identified for investigation and/or whose prescriptions it has blocked.

XI. PROACTIVE DUE DILIGENCE AND SITE VISITS

A. During the term of this Order, the Defendant shall conduct periodic proactive compliance reviews of its retail pharmacy stores in the County to assist with the identification of potential compliance issues related to the dispensing of Designated Controlled Substances at its retail pharmacy stores in the County. This may be satisfied by the use of algorithms, or other electronic means, to analyze data associated with each pharmacy to identify particular pharmacies for review. Documentation of any resulting reviews shall be maintained by the Defendant and made accessible to all Controlled Substance Compliance Department personnel upon request for the duration of this Order.

B. During the term of this Order, the Defendant's field personnel shall also conduct site visits to each of its retail pharmacy stores in the County each year for the duration of the Order. Operating procedures shall specify that any concerns identified with the dispensing of Designated Controlled Substances shall be reported to the Controlled Substance Compliance Department. The Controlled Substance Compliance Department shall maintain documentation of any such reported concerns.

C. During the term of this Order, to the extent not already in place, the Defendant shall put in place processes to oversee inventory, record keeping, and theft and loss prevention controls at its retail pharmacy stores in the County.

D. The CSCP Policies and Procedures shall require that site visit reports, if any, related to the dispensing of Designated Controlled Substances shall be maintained by the Defendant and provided to all Controlled Substance Compliance Department personnel for the duration of this Order and an annual report shall be provided to the Court.

XII. CONTROLLED SUBSTANCE DISPOSAL

A. The Defendant's retail pharmacies in the County shall make available or display information to all Patients receiving a Designated Controlled Substance about the need to dispose and the proper disposal of unused Controlled Substances and the availability of disposal boxes, pouches or containers for purchase from the Defendant, or other products commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home.

B. At each of its retail pharmacies in the County, the Defendant shall make available to Patients at its actual cost (per generally accepted accounting principles) a pouch or other container or product commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home. The Defendant shall maintain sufficient written documentation supporting its actual cost for the duration of this Order.

XIII. NALOXONE DISPENSING

A. To the extent not already in place, the Defendant shall obtain a non-patient-specific standing order covering each of its retail pharmacies in the County allowing for the dispensing of naloxone or other overdose reversal medications to the fullest extent allowable under Ohio law.

B. To the extent that a County and/or the State of Ohio obtain or enter into an agreement with a manufacturer of naloxone or other overdose reversal medication to provide naloxone or an overdose reversal medication to the County and/or State for free or at cost, the Defendant shall dispense that naloxone or other overdose reversal medication at its actual cost for dispensing that naloxone or other overdose reversal medication (time and expense). Upon request by the County and/or State to dispense such medication, in the course of arranging logistics with the County and/or State, the Defendant shall provide the County and the Court with its calculation of the actual cost to dispense.

XIV. FRAUD, THEFT AND LOSS PREVENTION

In addition to complying with all fraud, theft and loss procedures, policies and precautions required by state and federal law, the Defendant shall maintain information regarding the receipt and disposition of inventory of all Designated Controlled Substances for each retail pharmacy in the County.

XV. REPORTING TO LAW ENFORCEMENT

To the extent not already in place, the Defendant shall implement standard operating procedures directing its employees to report any confirmed forged prescriptions to state or local law enforcement authorities within 7 days of completing any review of such prescription or conduct. Lake and Trumbull Counties shall each provide appropriate contact information for such reports. The Defendant shall keep a record of all forged prescriptions in its database accessible to all pharmacists in the area and shall track all reports made to the DEA, local law enforcement and state agencies concerning Designated Controlled Substances. The Defendant shall comply with all statutes and regulations requiring the reporting of thefts and losses of Controlled Substances.

XVI. ENFORCEMENT OF ORDER TERMS

A. Notice of Potential Violations and Opportunity to Cure.

1. A “Potential Violation” occurs when a County determines, after appropriate investigation and due diligence, that a Defendant is not in substantial compliance with a material aspect of this Order. A Potential Violation may be for a single retail pharmacy.

2. Potential Violation Discovered by a County.

a. In the event a Potential Violation is identified by a County, the County shall notify the Defendant and the Court in writing (the “County Notice”).

b. Within thirty (30) days of receipt of the County Notice, the Defendant shall provide a written response to the County and the Court. The response shall include the Defendant’s position as to the act(s) of non-compliance with this Order’s Terms, including, possibly, a statement setting forth why the Defendant believes it is in substantial compliance with the relevant provision(s) or a statement explaining how the Potential Violation has been addressed.

c. If the County and/or the Court wish to meet with the Defendant, the Defendant shall promptly make itself available for such a meeting.

3. If, after review of a written response and any meeting, the Court believes that a Potential Violation is ongoing or has not been substantially addressed, the Court will:

- a. Provide written notice to the Defendant, and
- b. Work in conjunction with the County and the Defendant to devise, within thirty (30) days, a corrective action plan (“Corrective Action Plan”) to remedy such Potential Violation, including a reasonable period for implementation of such plan.

4. Within 60 days after implementing the Corrective Action Plan, the Defendant will provide a written compliance update to the County and the Court and make itself available to meet if requested.

- a. If after reviewing the compliance update and any meeting, the County believes a Potential Violation remains ongoing or has not been substantially addressed, the County may seek to enforce this Order before the Court.
- b. In the event the Court agrees that a Potential Violation remains ongoing or has not been substantially addressed, the Court may order compliance with this Order and may award any other relief permitted by law.

5. If a Defendant fails or refuses to provide a written response, to devise or implement a Corrective Action Plan or to provide a compliance update as required by subsections A(2), A(3) and/or A(4), upon a request made by the County, the Court may order compliance with this Order and may award any other relief permitted by law.

6. If, after review of a written response and any meeting, pursuant to subsection A(2) or A(3), above, the Court concludes that a Potential Violation is not ongoing or has been substantially addressed, the Court will provide written notice of this conclusion to the Defendant as soon as reasonably possible.

B. Enforcement Action.

The County will follow the entire process outlined above prior to taking any other court or administrative action, except the County may pursue an action that it concludes in good faith is necessary to address (i) an immediate threat to the health, safety, or welfare of the citizens of the County, or (ii) a public emergency requiring immediate action. The County will make best efforts to provide reasonable notice to the Defendant prior to initiating any such action.

XVII. COMPLIANCE CERTIFICATION

A. The Defendant's Chief Controlled Substance Compliance Officer shall, after diligent inquiry, complete an annual compliance certification.

B. The certification shall be provided to the Court annually for the duration of this Order.

C. The certification shall state:

"I understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include promoting compliance with regard to the [insert name of department] with all applicable statutory requirements, obligations of the Order, and applicable policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] is in compliance with the obligations of the Order. I understand that this certification is being provided to and relied upon by the U.S. District Court for the Northern District of Ohio."

D. If the Chief Controlled Substance Compliance Officer is unable to provide such a certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above to the Court.

E. Upon written demand by a County or the Court, the Defendant shall provide within a reasonable time after request the below materials.

1. Any specific, non-privileged documents reviewed by the Chief Controlled Substance Compliance Officer solely to make his/her certification, not including documents reviewed in the course of his/her duties throughout the year that provide him/her with relevant knowledge;

2. The current versions of the CSCP Policies and Procedures that are required by this Order;

3. The names of Ohio Prescribers of Designated Controlled Substances who the Settling Pharmacy has flagged for investigation and/or whose prescriptions it has blocked as part of its Prescriber Review Process; or

4. With regard to a particular retail pharmacy store in a County, any non-privileged reports related to that pharmacy store prepared pursuant to the processes outlined in Section XI.A.

F. Nothing in this Order shall be interpreted to abrogate the Defendant's applicable privileges or protections from disclosure, including without limitation those related to the attorney-client privilege, the attorney work product doctrine, and the patient-safety work product privilege. Nothing in this Order shall require the Defendant to provide or produce any such privileged or protected materials.

G. To the extent the above records contain personal health information of patients, the personal health information of patients shall be redacted and the presence of personal health information shall not be a reason to not produce any category of documents. To the extent that city, state, or zip code related information is contained within the above records and does not constitute personal health information of patients, the Defendant shall provide such information upon written request.

XVIII. RECORDKEEPING

The Defendant shall retain records they are required to create pursuant to its obligations hereunder, including documentation of the resolution of Red Flags and/or Refusals-to-Fill, in an electronic or otherwise readily accessible format. In addition to the prescription data regularly provided to the State of Ohio through its prescription drug monitoring program and all of the other records to which the State of Ohio has access under its pharmacy regulations, including without limitation through its on-site inspections of retail pharmacies, the County shall have the right to review the CSCP Policies and Procedures discussed herein. Nothing in these terms shall prohibit the County from issuing a lawful subpoena for records pursuant to an applicable law.

XIX. CHANGES AND MODIFICATIONS

A. The Court may, under its continuing jurisdiction over the abatement relief awarded, amend or modify this injunctive relief order as required in the interest of justice.

B. Nothing in this Order shall be construed to prohibit the Defendant from implementing improvements or enhancements or from otherwise evolving its systems and practices.

IT IS SO ORDERED.

/s/ Dan Aaron Polster

DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: February 10, 2023